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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,617	11/04/2005	Rachel Mary Haywood	70027880-0010	1759

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EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,617	HAYWOOD ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *9-11,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 15-17* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8, 12, and 15-17 in the reply filed on 1/22/08 is acknowledged. The traversal is on the ground(s) that the claims include many common technical features beyond those mentioned by the Examiner. Applicants cite technical features common between Groups I and II (page 3, line 19 - page 4, line 16), and also assert that all of the technical features of claim 12 (Group I) must correspond to technical features of claims 13 and 14. This is not found persuasive because the technical features cited by Applicants as being required for Groups I and II are not required for Group III, and the claims of Group III are not limited to the technical features of claim 12. Claims 13 and 14 are drawn to a sunscreen composition comprising a UVASPF or FRPF; the phrase "that has been assigned according to the method of claim 12" in claim 13 is a process step. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP 2113. Therefore, the technical feature common to all groups is a sunscreen composition comprising a UVASPF or FRPF. As stated previously,

> the special technical feature common to all of the groups cannot be considered a patentable advance over the art given that said feature, namely the sunscreen preparation or other skin preparation, is old. For example, US Patent 5,705,146 discloses sunscreen compositions

having an SPF in the UVA range (see col. 3, lines 10-15). Additionally, US Patent 5,968,485 discloses sunscreen compositions having a desired level sun protection factor and a desired level of UVA protection, citing that "SPF" is a commonly used measure of photoprotection of a sunscreen (see col. 4, line 58 – col. 5, line 10).

The requirement is still deemed proper and is therefore made FINAL.

2. **Claims 9-11, 13, and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.** Applicant timely traversed the restriction (election) requirement in the reply filed on 1/22/08.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

4. Claim 12 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-8 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurkiewicz et al., "EPR Detection of Free

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Radicals in UV-Irradiated Skin: Mouse *Versus* Human", *Photochemistry and Photobiology*, 1996, 64(6): 918-922, in view of Robinson, US Patent 5,968,485.

The claimed invention is drawn to a method as described in claims 1, 15, and 16:

> 1. (Original) A method for measuring the effectiveness of a sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation, the method comprising:
>
> irradiating a sample of human skin or of an effective substitute therefor (herein: "skin"), shielded with the sunscreen composition or other skin preparation to be tested, with UV radiation comprising UVA wavelengths, and determining by electron spin resonance (ESR) spectroscopy the level of induced production of ascorbate radical in the shielded skin; and
>
> determining a quantitative measure of the effectiveness of the sunscreen composition in reducing the exposure of human skin to UVA radiation by comparison of the said level of ascorbate radical production in the shielded skin with the level of ascorbate radical production induced in reference skin under substantially quantitatively comparable conditions.
>
> 15. (Currently Amended) ~~Use of differential ESR spectroscopy in a~~ A method for measuring the effectiveness of a sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation comprising the step of using differential ESR spectroscopy to determine an induced ascorbate radical production level.
>
> 16. (Currently Amended) The ~~use~~ method according to claim 15, wherein the differential ESR spectroscopy is used to quantify UVA-induced ascorbate radical production in skin shielded by the said composition or other skin preparation, in comparison with reference, preferably unshielded, skin.

Jurkiewicz et al. teach EPR (i.e., ESR) detection of ascorbate free radicals in UV-irradiated skin (see abstract). A sample of human skin was

irradiated with UV radiation comprising UVA wavelengths, either unshielded or shielded with a shield such as a filter (see page 919, third full paragraph), and the ascorbate radical EPR signal was determined. Jurkiewicz et al. also teach irradiating a sample to which the photoprotective agent Desferal has been topically applied, and with which a 305 nm UV cutoff filter was used (page 921, first paragraph).

Jurkiewicz et al. do not teach the use of a photoprotective (i.e., sunscreen) agent in the UVA range (320 - 400 nm), and do not specifically state that a quantitative measure of the effectiveness of the suncscreen composition was determined.

Robinson teaches UVA-absorbing dibenzoylmethane sunscreen actives which absorb UV radiation having a wavelength of from about 320 nm to about 400 nm (col. 3, lines 50-55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select a sunscreen active in the UVA region (e.g., the sunscreen active taught by Robinson) to be used on the shielded skin. One skilled in the art would have been motivated to do so because the process of Jurkiewicz et al. is taught to be used on unshielded skin in both the UVA and UVB ranges, and because the process is also taught to be used on shielded skin. Therefore, it naturally follows that one skilled in the art would also use the process taught by Jurkiewicz et al. for

measuring the effectiveness of a sunscreen active in the UVA region, such as the sunscreen active taught by Robinson.

Regarding the step of determining a quantitative measure of the effectiveness of the sunscreen composition in reducing the exposure of human skin to UVA radiation, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to compare levels of ascorbate radical production in the shielded and reference skin samples. Comparing the data obtained between a sample and its comparable reference is generally conventional and well within the capacity of one of ordinary skill in the art, as substantiated by Applicant's remarks on page 14 of the specification.

Regarding claims 2 and 3, Jurkiewicz et al. teach that the skin sample may be irradiated in the absence of a photoprotective agent (i.e., sunscreen composition). Additionally, the skin sample may be irradiated with a shield where wavelengths below 400nm are filtered out (see Materials and Methods, page 919). The steps of measuring a reference using conditions (such as UV radiation and ESR conditions) comparable to those used with the test sample, are conventional steps followed when comparing a test sample to a reference sample, and well within the capacity of one of ordinary skill in the art.

Regarding claims 4 and 5, Jurkiewicz et al. are silent with respect to whether or not the test and reference skin samples are the same. However, one skilled in the art of EPR spectroscopy would be able to control the dose of UVA radiation within the parameters of routine experimentation, such that the skin samples could be used once (wherein the test and reference skin samples are different but functionally comparable), or more than once (wherein the test and reference skin sample are the same).

Regarding claims 6 and 7, Jurkiewicz et al. teach the UV-induced production of other radicals when the skin samples are irradiated in the presence of a spin trap molecule (page 920).

Regarding claims 8 and 17, the ranges disclosed for UV radiation and UVA radiation are the standard accepted wavelength ranges for UV and UVA radiation, and well within the capacity of one skilled in the art. For example, Robinson teaches that the UVA-absorbing sunscreen active absorbs UV radiation having a wavelength of from about 320 nm to about 400 nm (col. 3, lines 52-55).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose

telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Michael P Woodward/
Supervisory Patent Examiner,
Art Unit 1615